EPA RESPONSES TO QUESTIONS FROM LEWIS AND CLARK COUNTY HEALTH BOARD
Based on meeting held December 17, 2007

1. **Discuss the rationale for EPA's decision (on a national level) against lowering the "level of concern" for lead in children's blood (now 10 ug/dL) and discuss implications of a site-specific lowering of the "level of concern" to 5 ug/dl or 2 ug/dl.**

The rationale for EPA and CDC not lowering the blood lead level of concern below 10 ug/dL is addressed by the Centers for Disease Control and Prevention in their 2005 document entitled *Preventing Lead Poisoning in Young Children.* It reads as follows:

"In 1991 the CDC recommended lowering the level for individual intervention to 15 ug/dL and implementing community-wide primary lead poisoning prevention activities in areas where many children have blood lead level greater than 10 ug/dL. Some activities, such as taking an environmental history, educating parents about lead, and conducting follow-up blood lead monitoring were suggested for children with blood lead levels greater than 10 ug/dL. However, this level, which was originally intended to trigger communitywide prevention activities, has been misinterpreted frequently as a definitive toxicologic threshold. Evidence exists of adverse health effects in children at blood lead levels less than 10 ug/dL. The available data are based on a sample of fewer than 200 children whose blood lead levels were never above 10 ug/dL and questions remain about the size of the effect. At this time there are valid reasons not to lower the level of concern established in 1991 including the following:

- No effective clinical or public health interventions have been identified that reliably and consistently lower blood lead levels that already are less than 10 ug/dL.
- No one threshold for adverse effects has been demonstrated. Thus the process for establishing a lower level of concern would be arbitrary and no particular blood lead level cutoff can be defended on the basis of the existing data. In addition, establishing a lower level of concern may provide a false sense of safety about the well being of children whose blood lead levels are below the threshold.
- The adverse health effects associated with elevated blood lead levels are subtle. Individual variation in response to exposure and other influences on developmental status, make isolating the effect of lead or predicting the overall magnitude of potential adverse health effects exceedingly difficult.
- Efforts to identify and provide services to children with blood lead levels less than 10 ug/dL may deflect needed resources from children with higher blood lead levels who are likely to benefit most from individualized interventions."

If the health-based goal were reduced from 10 ug/dL to either 5 or 2 ug/dL, and if the IEUBK model were used to identify the target level of lead in soil, the effects would be as follows:

Target 95th ug/dL	Target GM ug/dL	Target Soil mg/kg
10	4.62	402
5	2.31	137
2	0.92	-8

At the East Helena site, EPA has already chosen to set a Remedial Action Objective that, based on on-going blood lead surveys, there should be no more than a 5% probability that a child will have a blood lead value greater than 5 ug/dL. This is a goal substantially more stringent than the national goal (no more than a 5% chance of exceeding 10 ug/dL), and this goal has been achieved in East Helena in every year from 2002 to the present.

2. Discuss in greater detail the extent to which education and outreach are thought to affect children's blood lead levels in East Helena.

We believe that it is unlikely that the extremely low blood lead levels observed in East Helena are due to public education and awareness. While EPA agrees that the current program of lead education is valuable in providing citizens with knowledge they may utilize to reduce risk from lead exposure, EPA does not believe that this program could be responsible for generating a bias in the data set that could account for the current observations. From 1989 – 1991, EPA conducted the Urban Soil Lead Abatement Demonstration Project in Baltimore, Boston, and Cincinnati (USEPA, 1996). The study examined the effectiveness of soil, interior dust and lead abatement in reducing children's blood lead levels. In the control groups which received no abatement, but were aware of the study and the hazards associated with lead, the investigators found significant decreases in children's blood lead levels in the first 6 months. These blood lead levels rebounded to pre-study levels by the 2nd year of the study. This study suggests that awareness of lead hazards may result in temporary changes in behavior which reduce exposure to lead hazards, but the changes are not long term. The blood lead studies in East Helena have been conducted for more than 15 years. The results are consistently low, and the trend is downwards. It is unlikely that they are influenced to any large extent by public awareness. Moreover, the blood lead data for East Helena children indicate that current exposure levels are sufficiently far from a level of concern that even if there were some small bias in the data (this is not thought to be true), the judgment that the blood lead data indicate the current soil cleanup program is effective remains valid.

<u>Reference</u>

US Environmental Protection Agency (1996). Urban Soil Lead Abatement Demonstration Project Volume I: EPA Integrated Report. National Center for Environmental Assessment, Research Triangle Park, NC. EPA/600/P-93/001aF.

3. Can the need for institutional controls be reduced (minimized) by adopting a more stringent soil cleanup action level? Provide an in-depth discussion and breakdown of each

component of institutional controls, including estimated short- and long-term costs per component. For clarification, Kathy Moore added: The Board seeks assurances that funding will be adequate, and that EPA and MDEQ will "be there" to provide assistance, advice and coordination.

EPA has demonstrated that, irrespective of the soil cleanup action level, the need for both short-term and long-term institutional controls remains unchanged. Institutional controls are best defined as remedy protection measures, and EPA has described in the Proposed Plan, Decision Summary and Responsiveness Summary that ICs are an essential part of the remedy.

As for the second part of the question, EPA has provided a "breakdown" of ICs by their components in the Decision Summary and Responsiveness Summary. However, cost estimates cannot be prepared by EPA alone. The annual cost for maintaining the Lead Education and Abatement Program is approximately $140,000. The extent to which ICs administration will be carried out by the lead abatement program, or perhaps another county program, is unknown. Also unknown is whether or not the county will seek fees to carry out ICs that are routinely conducted by the county already (e.g., subdivision planning and reviews, best management practices and weed control on undeveloped lands, maintaining a GIS database to keep track of sampling results, etc.). These are but two examples of cost estimates that EPA cannot provide without the county's input.

EPA is prepared to resume work with the county, as before, once the record of decision is issued and throughout the remedial design and remedial action construction phases of remedy implementation. With input from the county, and exchange of information, the ICs components may be refined and costs estimated. EPA anticipates that the Board of Health will resume deliberations regarding its vital role in administering ICs. The Board may adopt regulations and develop policies regarding ICs.

It would be both presumptuous and very likely unsuccessful for EPA to "specify" or "prescribe" ICs beyond the extent to which ICs have to date been identified. Thus, development, funding and administration of ICs must be a cooperative effort. EPA has numerous times demonstrated its commitment to supporting the county, and EPA will continue to work with and support the county for as long as is necessary.

4. Some East Helena children have been tested multiple times. How were multiple tests treated in the representations of data to date? Plot on an aerial photo data that represent children who were tested multiple times. Scott Brown and Kathy Moore discussed this request with Jan Williams and Debb Tillo and the following conclusions were made: EPA's contractor has access to the county-managed data base. EPA can plot these data on an aerial photo (in a manner similar for all children tested between 1995 and 2006, irrespective of how many times each child had been tested). However, EPA's contractor

will need assistance from Jan and Debb, as before, and from the County's GIS unit, also as before. The new plots should be considered in combination with existing plots.

When an individual child was tested more than one time, all values from the same child within the same calendar year were averaged. If a child was tested in more than one year, these values were kept separate when calculating yearly summary statistics and evaluating time trends.

Sheet 3 in the Record of Decision, prepared by the County, shows the locations of homes where one or more children had more than one blood lead value collected. As seen, the locations of homes where children have been evaluated more than one time are distributed across the city's many neighborhoods and outlying subdivisions in a manner that demonstrates a high degree of spatial representativeness.

In interpreting this information, it is useful to contemplate reasons why a child would have more than one blood lead result. EPA believes the most likely reason is that the first blood lead result would have been higher than what the parents felt was appropriate, and that follow-on tests were performed to determine if the first value was correct or to see if values decreased over time. However, a complicating factor in this analysis is the incentive program offered by the County, which may have encouraged some parents to have multiple tests of their children's blood lead, even when initial blood lead values were low.

Table 1 shows summary statistics that test this hypothesis. As seen, the data indicate children with high initial blood lead values tended to have more follow-up blood lead measurements (an average of 1.7 follow-ups per child) than children with lower initial blood lead values (about 0.3 follow-up visits per child). Note that this pattern may tend to bias the blood lead data set in an upwards (overestimation) direction, since children with elevated values contribute data more frequently than children with lower values.

5. Reexamine the apparent "upward trend" of higher blood lead values for East Helena children observed in 2006, as compared to previous years. Kathy Moore's follow-up memo (attached) clarifies this point:

> ***I wrote, "there are more children over 4 (ug/dl) than there were 6 years ago." This may be what Vic was talking about. I also wrote that there is, "a 30% increase in kids over 4, the trend is increasing." I believe this addresses your question about the statistical bump in 2005.***

Table 2 shows the number and fraction of children with blood lead values above 4 ug/dl as a function of year. As seen, the percentage of children above 4 ug/dl trended downward through the 1990s. This initial downward trend, EPA believes, is explained primarily by reductions of fine particulates being emitted from plant operations. By 1998-2000, Asarco began meeting the federal and state standards for lead in air. Then as seen in Table 2, the percentage of children above 4 ug/dl decreased substantially more in 2001 and has since remained low. It is not coincidence that this decrease corresponds to the time frame in which the smelter ceased operations and all emissions from the smelter to the surrounding community were eliminated.

EPA does not interpret the data as being an "upward trend" in either 2005 or 2006. And, the fraction of children above 4 ug/dl in 2006-2007 is not higher than the fraction of children above 4 ug/dl in 2000-2001. In 2004, the fraction was slightly higher (7%) than in the two preceding years (0-3%), but that did not continue into 2005, 2006, or 2007. It is important to recognize that yearly statistics of this type are inherently variable, and it would not be appropriate to make judgments about trends based on one or two years of data. Rather, in order to determine the presence of time trends, the data must be considered in their entirety.

6. Update the multiple regression analysis graph (1993 report, using Lewis and Clark County's 1991 blood lead data) to include all of the more recent matched pairs of soil-lead and blood-lead data and more recent air pathway inputs after 1993. Recalculate the estimated contribution arising from exposure to soils (i.e., the contribution to actual, observed blood lead levels) based on the more recent data set.

Multi-variate regression to quantify the relationship between blood lead and the concentration of lead in soil and air is confounded if blood lead values are changing because of factors other than changes in soil or air. In particular, it is well established that there has been an on-going downward trend in blood lead levels at the national level due the success of several national programs that have reduced lead exposures from food, water, automobile exhaust, and consumer products. Therefore, it is not appropriate to combine data across different time periods because to do so would tend to obscure any relationships that may exist.

Rather, it is more appropriate to analyze the data in a series of time strata. This helps minimize the confounding caused by the decreasing trends in national blood lead levels. Results of an analysis of this type are shown in Figure 2. In this graph, blood lead values, stratified by calendar period, are plotted as a function of soil lead. Stratification based on air lead is not included because air levels are now quite low and are unlikely to be a significant contributing source of elevated blood leads. Based on data from four air monitoring stations in East Helena in 2000 and 2001, the average concentration of lead in air was about 0.5 ug/m^3. Based on the IEUBK model, the contribution of lead in air at a level of 0.5 ug/m^3 is less than 0.5 ug/dL.

If soil lead is a major source of blood lead, it is expected the data will tend to display an upward trend, with a slope similar to that predicted by the IEUBK model (about 6.5 to 8.1 ug/dL per 1000 ppm). However, as shown in the figure, the slopes of the lines in all years are quite shallow, with slopes lower than predicted by the IEUBK model. Based on all of the data, the average slope is actually negative (-1.4 ug/dL per 1000 ppm). This value is perhaps unduly influenced by the high negative slope observed in 2005, which is based on only 4 values. If this slope is excluded, the average is very close to zero[1]. EPA interprets these data to indicate that, under recent site conditions, lead in soil is only one of many sources of blood lead, and that its contribution to blood lead in children is small compared to other sources.

7. Reexamine all other relevant data pertaining to sources and pathways of lead exposure, particularly results of numerous in-home environmental assessments conducted by health professionals. Does the weight of evidence suggest that attic dust, heating system dust, unfinished basements, carpets or furniture, wall insulation, hobbies, garden vegetables, pets, parents' workplace, interior or exterior paint, or any other possible sources or pathways do contribute or do not contribute to children's blood lead levels?

A data table was provided to EPA by the County that summarized the results of 111 Exposure Assessment (EA) visits. Of these 111, EAs, 25 occurred at locations where no data were available on the level of lead in the soil. Of the 86 properties for which yard lead levels are known, about 2/3 had soil that exceeded EPA's cleanup triggers for lead, and where the soil had either been cleaned up at the time of the visit or were scheduled for cleanup.

For each EA, information was provided regarding the occurrence of non-soil sources of lead exposure such as leaded paint, elevated lead in indoor dust, lead in drinking water, a parent who worked at the smelter, etc. Of these EAs, a blood lead value (the highest observed at the property) was reported for 63 visits. Table 3 summarizes data on the frequency that non-soil sources were identified, stratified as a function of maximum blood lead for these 63 EAs. As seen, the average number of alternative sources tends to increase as the maximum observed blood lead increases. For the highest category (maximum blood lead > 10 ug/dL), alternative sources of lead exposure were identified in 90% of the visits, with an average of 1.6 alternative sources per location. These results support the conclusion that there are multiple sources of lead exposure in the community, and that there is an association between alternative sources (i.e., sources other than yard lead) and the occurrence of elevated blood lead values.

8. Reexamine soil arsenic data. Provide all pre-sample results for arsenic and show distribution contours for soil arsenic, at varying concentrations, in the same manner as distribution contours are provided for lead at varying concentrations. Kathy Moore's follow-up memo (attached) clarifies this point.

> ***Also, the questions about how the arsenic level was chosen and is it a scientifically supported cleanup level or a cleanup level that is coincidental to lead levels is still a big question.***

The method used to compute the risk-based concentration (RBC) for arsenic is based on standard EPA methods. The equation is:

[1] Note that it is not possible to plot a line that displays the average slope on the graph because the intercept term is time-dependent and so the position of the line on the graph would be arbitrary.

$$RBC = \text{target risk} / (HIF \cdot RBA \cdot oSF)$$

where:

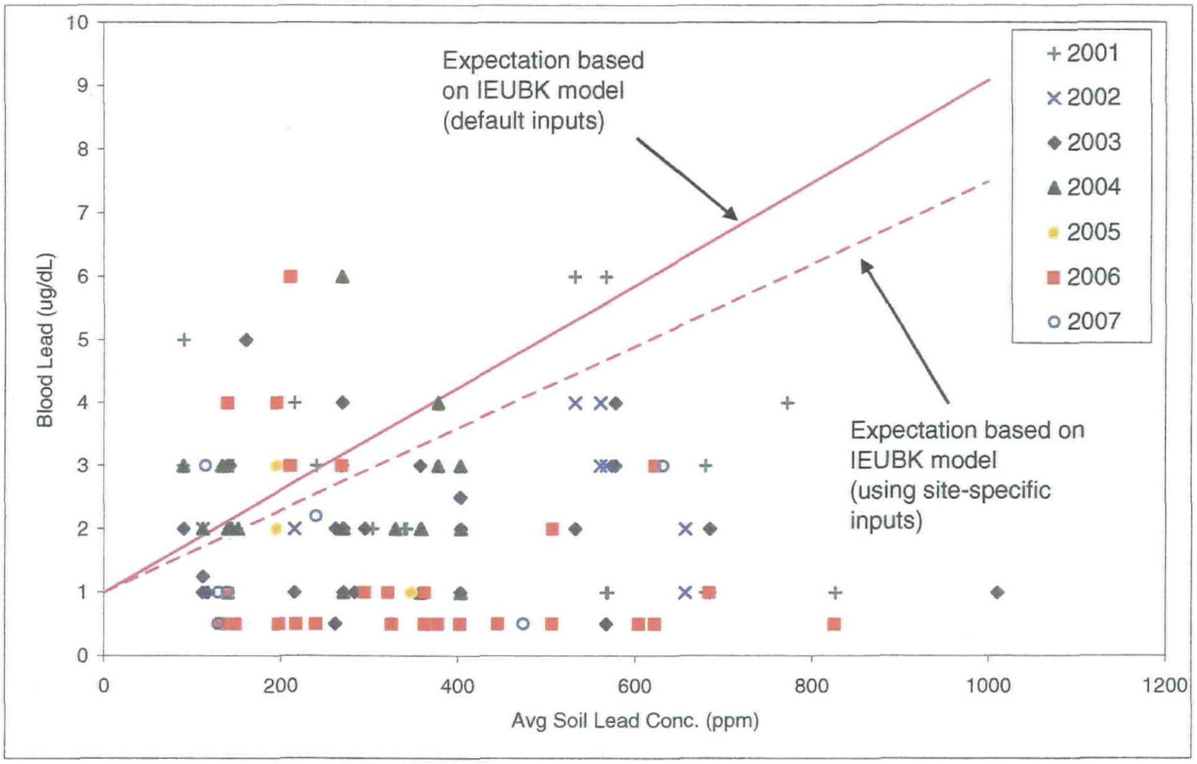
HIF	=	Human Intake Factor. This describes the average amount of soil ingested per day (kg/kg-day).
RBA	=	Relative bioavailability of arsenic in soil compared to water
oSF	=	Oral slope factor for arsenic $(mg/kg\text{-}day)^{-1}$

The target risk chosen was 1.499E-04, since this will yield the concentration value where risk change from 1E-04 (acceptable) to 2E-04 (unacceptable). The HIF is based on standard USEPA assumptions about residential exposure to soil (350 days year for 30 years, with intake rates of 200 mg/day as a child (age 0-6) and 100 mg/day as an adult (age 7-30)). Based on measurements of arsenic RBA an many mining sites, a value of 50% was used. This is considered to be conservative, since nearly all measured values are lower than this. Likewise, based on data from numerous other mining and smelting sites, the concentration of arsenic in indoor dust was assumed to be 50% of that in outdoor soil. This too is considered to be conservative, since the observed ratios are nearly always lower than this. Based on these inputs, the RBC for arsenic in residential soil is 176 ppm.

Figure 3 shows the relationship between arsenic and lead in soil samples from the site. As seen, although there is variability, there is a clear relation between the two. This implies that, on average, elevated levels of arsenic will be associated with elevated levels of lead. In order to investigate what the levels of arsenic would be after implementation of lead-based property cleanups, the soil database was queried to identify the total number of properties where the yard-wide average arsenic concentration exceeded 176 ppm. Six such properties were identified. After implementation of the lead-based cleanup, all six of these properties will be cleaned up and no properties will exceed an average value of 176 ppm. These results support the conclusion that a clean-up approach based on lead will adequately address any concerns that may exist over arsenic.

FIGURE 2

RELATION BETWEEN AVERAGE SOIL LEAD AND BLOOD LEAD VALUES FOR CHILDREN (0 to 84 mos) AT UNREMEDIATED PROPERTIES IN EAST HELENA 2001 - 2007



Year	N	Slope ug per 1000
2001	18	-0.70
2002	10	0.08
2003	37	0.01
2004	22	0.90
2005	4	-9.82
2006	33	-1.80
2007	7	1.44

Average slope (ug/dL per 1000 ppm)

All years	-1.41
Excluding 2005	-0.01

IEUBK Predicted Slope (ug/dL per 1000 ppm)

All default inputs	8.10
Site-specific inputs	6.50

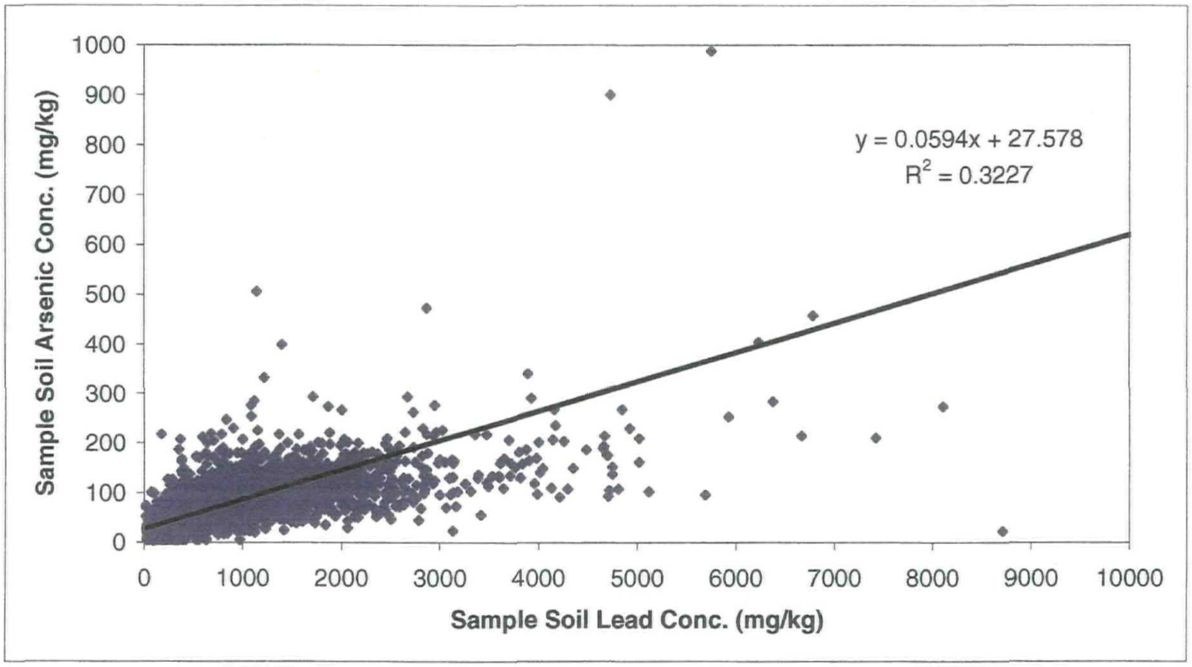
NOTES:

If lead in soil is a significant contributor to blood lead in children, then it is expected that a plot of blood lead vs soil lead will have an upward trend. Based on the IEUBL model, this trend should be about 6 to 8 ug/dL per 1000 ppm of lead in soil. Because of the trend toward decreasing blood lead values nationally, the data must be stratified by year to have a chance to see any trends that are present. As seen, most of the observed trends are much lower than predicted by the IEUBK model. This suggests that the contribution of soil lead to blood lead is relatively small within the range of 0- 1000 ppm.

FIGURE 3

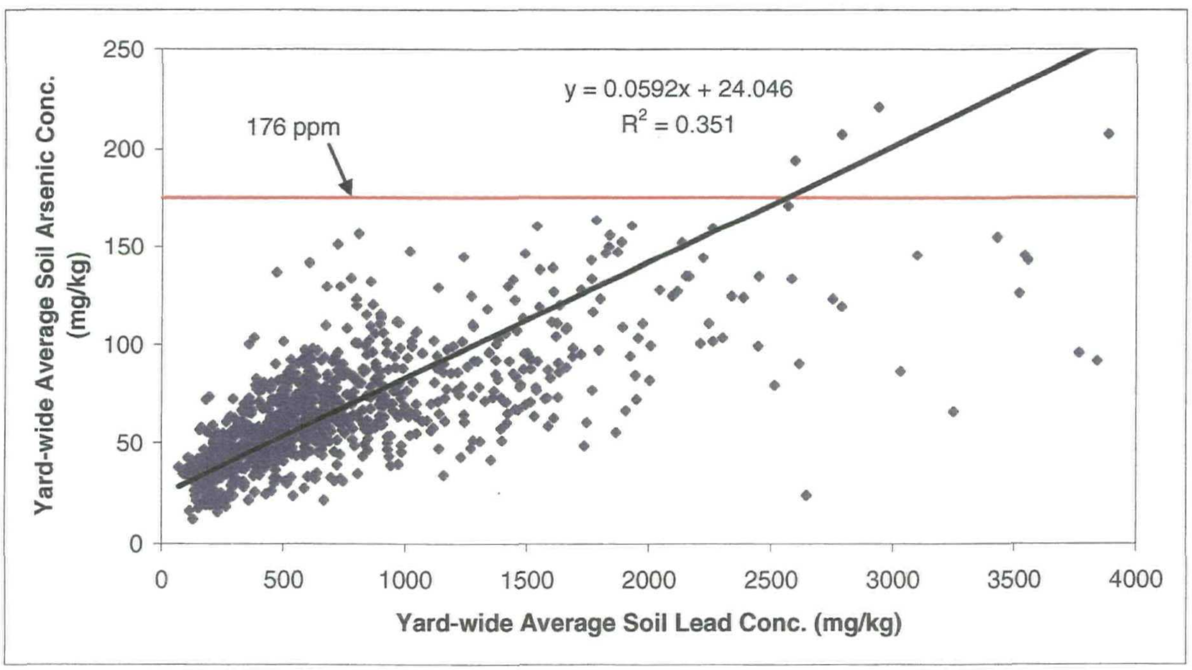
Correlation of Lead and Arsenic Concentrations in Soil

Panel A: By Sample



5 data points off-scale: 1) Pb - 27,304 mg/kg, As - 1023 mg/kg; 2) Pb - 9198 mg/kg, As - 3179 mg/kg
3) Pb - 8978 mg/kg, As - 2957 mg/kg; 4) Pb - 8224 mg/kg, As - 2655 mg/kg; 5) Pb - 7574 mg/kg, As - 2073 mg/kg

Panel B: By Yard-wide Average



2 data points off-scale: 1) Pb - 6655 mg/kg, As - 1837 mg/kg; 2) Pb - 7293 mg/kg, As - 307 mg/kg

TABLE 1.
RELATION BETWEEN INITIAL BLOOD LEAD RESULT
AND NUMBER OF REPEAT MEASUREMENTS

Initial PbB Result (ug/dL)	N Children	N Follow-up PbB Measurements							Avg. Follow-up Visits
		0	1	2	3	4	5	6	
0-3	550	436	79	24	6	3	2		0.30
3-6	206	154	45	4	1	1		1	0.32
6-10	84	47	20	14	2	1			0.69
>10	24	7	8	2	4		2	1	1.67

TABLE 2

FRACTION OF CHILDREN ABOVE 4 UG/DL AS A FUNCTION OF YEAR

Year	Number of Children	PbB ≤ 4 ug/dL	PbB > 4 ug/dL
1991	71	49%	51%
1992	15	13%	87%
1993	10	20%	80%
1994	24	54%	46%
1995	75	49%	51%
1996	84	67%	33%
1997	71	63%	37%
1998	116	75%	25%
1999	51	35%	65%
2000	143	73%	27%
2001	93	86%	14%
2002	36	100%	0%
2003	159	97%	3%
2004	107	93%	7%
2005	9	100%	0%
2006	109	98%	2%
2007	7	100%	0%

TABLE 3
SUMMARY OF ENVIRINMENTAL ASSESSMENTS FOR ALTERNATIVE SOURCES OF LEAD EXPOSURE

PbB (ug/dL)	N	Number of Alternate Sources								
		0		1		2		3		Count weighted average
0 - 6	35	19	54%	13	37%	3	9%	0	0%	0.54
>6 - 10	18	8	44%	5	28%	2	11%	3	17%	1.00
>10	10	1	10%	3	30%	5	50%	1	10%	1.60
Total	63	28	44%	21	33%	10	16%	4	6%	0.84